The requirement submits that claims 1-12 and 21-28 are generic.

The requirement Submits that Species I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

ELECTION

In order to be responsive to the species requirement, Applicants elect, with traverse, the invention set forth in Specie II, of which claims 1-12 and 17-28 read on (claims 1-12 and 21-28 being generic).

TRAVERSE

Notwithstanding the election of the claims of Specie II, in order to be responsive to the Species Requirement, Applicants respectfully traverse the Examiner's requirement for Species Election.

The Examiner is reminded that in National Stage Applications (*i.e.*, "371 Applications"), such as the present application, the criteria set forth in 37 C.F.R. § 1.475 determining unity of invention **must be considered**. The present Restriction Requirement fails to fully follow 37 C.F.R. § 1.475 because it appears to ignore at least 37 C.F.R. § 1.475(a).

Specifically, Applicants note that 37 C.F.R. § 1.475 provides:

Unity of invention before the International Searching Authority, the International Preliminary Examining Authority, and during the national stage.

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said

product, and an apparatus or means specifically designed for carrying out the said process.

- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicants point out that in determining unity of invention the criteria set forth in 37 C.F.R. § 1.475 must be considered. Thus, in stating the species requirement, the requirement must state why unity of invention is lacking at least under 1.475(a) and/or (b). Therefore, the restriction requirement is improper for not discussing the various sections of 1.475 and the details of why unity of invention is lacking. For example, the species requirement (at pages 2-3) only generally states that the groups "do not share the same or corresponding technical feature." In response, Applicants respectfully submit that the groups share the same or corresponding technical feature as provided in the independent claim, and thus unity of invention is not lacking. Thus, the present Species Requirement fails to properly follow 37 C.F.R. § 1.475.

In addition, 37 C.F.R. § 1.475 states that the expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, the instant requirement does not indicate how any aspect of Applicants' claims is not patentable over the prior art. In this regard, Applicants note that even if the restriction requirement is maintained, upon allowance of the claims of Specie II, the claims of Specie I should be rejoined and allowed.

Therefore, if the lack of unity of invention is maintained, the Examiner is respectfully requested to indicate how the Species Requirement complies with 37 C.F.R. § 1.475, otherwise, the Species Requirement should be **withdrawn**.

In view of the foregoing, it is respectfully requested that the Examiner reconsider the species requirement, and withdraw the same so as to give an examination on the merits on all of the claims pending in this application. In any event, the claims should be rejoined upon allowance of the elected claims.

Attorney Docket No.:7063.204-US

Page 4 of 4

371 National Stage of PCT/GB2003/004706

International Filing Date: October 31, 2003

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the Examiner's requirement for restriction is improper and should be withdrawn. If the Examiner has any questions, or wishes to discuss this matter, please call the undersigned at the telephone number indicated below.

Respectfully submitted,

Date: August 26, 2009 <u>/Wesley A. Nicolas, Reg. No. 56,129/</u>

Wesley A. Nicolas, Reg. No. 56,129

Novo Nordisk Inc.

Customer Number 23650

(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE